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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------------------------------------------------------------------|-------------|----------------------|----------------------|------------------|
| 10/608,518 | 06/24/2003 | Jaeho Kim | 279.312US2 | 9319 |
| 21186 | 7590 | 04/11/2006 | EXAMINER | |
| SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 121 S. 8TH STREET SUITE 1600 MINNEAPOLIS, MN 55402 | | | LAYNO, CARL HERNANDZ | |
| | | ART UNIT | PAPER NUMBER | |
| | | 3766 | | |

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|---------------------------|---------------------|
| | 10/608,518 | KIM ET AL. |
| | Examiner Carl H. Layno | Art Unit 3766 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 June 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,5-9,14 and 16-20 is/are rejected.

7) Claim(s) 2-4,10-13 and 15 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 24 June 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/24/03.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Information Disclosure Statement

1. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on June 24, 2003.

Drawings

2. Applicant's formal drawings were received by the Office on June 24, 2003. These drawings are approved by the Examiner.

Specification

3. The disclosure is objected to because of the following informalities:
-p.1, 1st paragraph, lines 1-2, the status of U.S. Patent Application No. 09/828,461, should be updated to reflect that it is now U.S Patent No. 6,584,350.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 5-9, 14, 16, 17, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayers et al (US 5,814,081) or White (US 5,562,709) in view of Borgerding et al (US 6,058,327).

In regard to claims 1, 9, and 17, the Ayers et al (US 5,814,081) patent describes an atrial cardioverter and the method of its operation, which appear to read upon applicant's claimed method steps. Specifically, Ayers et al '081 discloses an implantable stimulator (Fig.1) including an atrial sensing circuit **52,54**, a ventricular R-wave sensing circuit **56,58**, a defibrillation circuit **90,88,65**, timer circuits **53,60,69**, and a microprocessor controller **60**. In operation, the device detects atrial flutter/fibrillation using its atrial and ventricular sensing circuits (col.1, lines 23 – 59). R-wave detector **58** (Fig.1) includes a threshold circuit (col.4, lines 1-5) for setting an "upper and lower threshold" and generates an output when these thresholds are exceeded. Each time an R-wave is detected, an "inhibit stage" **69** starts a timer having an interval of between 250-600 ms during which no cardioverting energy may be applied (col.6, lines 47-63). Upon expiration of this interval cardioverting energy may be applied to the patient's atria via electrodes **40,42** in synchronization with an R-wave. This is accomplished with the help of synchronization stage **62** (col.5, line 66 – col.6, line 7).

In regard to claims 1, 9, and 17, the White (US 5,562,709) patent discloses an atrial defibrillator (Fig.1) also capable of performing the step of atrial fibrillation detection. See circuits **52,68,80**. This defibrillator also includes two ventricular sensing channels (RV-RV, RV-CS) having R-wave detection circuits **58,64**, respectively. These circuits are associated with a high threshold (**TH2**) and low threshold (**TH1**) value, respectively. See Fig.2 (col.8, lines 22-28). In use, R-waves detected by these circuits cause an interval timer **82** to start. Timer **82** times

a minimum interval criteria, which when completed, enables the device to deliver energy to the patient in synchronization with an R-wave (col.7, lines 15-20 and 35-40).

Unlike applicant's device, both Ayers et al and White remain silent with respect to the use of a "dynamically varying threshold".

The Borgerding et al (US 6,058,327) patent recites an implantable heart stimulation device whose R-wave detection circuits (Figs.3 and 4) utilize an automatic variable sensing threshold $V_s(t)$ in conjunction with a low threshold level S and a high threshold level B^*S (Fig.5). To have utilized a variable sensing R-wave threshold to be used in conjunction with the low and high voltage thresholds already present on the Ayers et al '081 and White '709 patents would have been obvious to one of ordinary skill in view of the teachings of Borgerding et al which states that this circuitry may be used with "any known cardioversion or defibrillation pulse control circuitry" (col.7, lines 11-13).

In regard to claims 5, 6, 19, and 20, applicant's attention is directed to the Borgerding et al '327 patent (Fig.5). The modified devices of White and Ayers et al read upon applicant's claims for the case when the low threshold S equals the dynamically varying threshold $V_s(t)$. In this case, the values of B and A for the high threshold (B^*S and A^*S) would represent percentages of the dynamically varying threshold $V_s(t)$.

In regard to claims 7, 8, 14, and 16, the Borgerding et al patent teaches the detection of both atrial and ventricular tachyarrhythmias based upon the detection of R-R intervals (i.e. ventricular rate) or P-P intervals (i.e. atrial rate).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 17, 18, and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 10, and 14, respectively, of U.S. Patent No. 6,584,350. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite the same structural features of an atrial sensing channel, a ventricular sensing channel, a shock pulse generator, and a controller “programmed to detect episodes of atrial fibrillation or other atrial tachyarrhythmias” and to “deliver an atrial defibrillation shock pulse synchronously with a detected R-wave” if threshold values and a minimum timer interval have been exceeded. Applicant’s depending claims 18 and 20 read upon claims 10 and 14 of the ‘350 patent *verbatim*.

Allowable Subject Matter

Art Unit: 3766

8. Claims 2-4, 10-13, and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Rajasekhar et al (US 6,249,701) patent is cited for its pertinent teaching of using a percentage threshold (Fig.5) in conjunction with a low threshold S and high threshold n^* s. Unlike applicant's device, however, these thresholds appear to apply only to atrial sensed signals not ventricular sensed signals.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carl H. Layno

**CARL LAYNO
PRIMARY EXAMINER**

CHL
4/6/2006